Region 2 Enforcement and Compliance Assurance Division

Air Compliance Branch

CAA Inspection Report

Inspection Date: September 8, 2022

Facility Name: Sterigenics US LLC

Facility Address: 84 Park Rd, Queensbury, NY 12804

ICIS-Air ID #: NY0000005534400029

Facility Contact: Justin Fitzpatrick	Interim General Manager	JuFitzpatrick@sterigenics.com
EPA Lead Inspector: Julian Velez	CAA Inspector	Velez.Julian@epa.gov
EPA Asst. Inspector: Victor Tu	CAA Inspector	Tu.Victor@epa.gov
State Inspector(s): Mike Sundberg, PE	NYSDEC Inspector	Mike.Sundberg@dec.ny.gov

Other Inspector(s): N/A

Pertinent Regulatory Requirements

- 40 C.F.R. 63 Subpart O – Ethylene Oxide Emissions Standards for Sterilization Facilities.

Summary of Observations

Environmental Protection Agency (EPA) inspectors Julian Velez and Victor Tu arrived at the Sterigenics facility in Queensbury, NY at 9:15 am. The inspectors met in the parking lot with NYS Department of Environmental Conservation (DEC) inspector Mike Sundberg and Mr. Justin Fitzpatrick (Interim General Manager – Sterigenics). The group entered a small waiting room and watched a video related to safety at ethylene oxide sterilization facilities. Mr. Fitzpatrick explained that the conference room was occupied at the time of the inspection and suggested the group meet in the break room; the inspectors agreed. The EPA inspectors presented their credentials to Mr. Fitzpatrick and Inspector Velez stated that the reason of the visit was to perform a Clean Air Act (CAA) inspection.

Sterigenics started operations in 1994; Sotera Health is their parent company. The facility performs sterilization of medical and a limited number of veterinarian devices and does not manufacture any devices/equipment. Inspector Velez asked Mr. Fitzpatrick for a process-flow diagram to better understand the process and equipment at the facility. Mr. Fitzpatrick provided the diagram and explained the process; in summary, Sterigenics receives the devices from the customers and places them in an area called “unprocessed storage.”

The products are then moved into the "Preconditioning rooms" that are kept at high heat/temperature and humidity. After this step, the products are transferred to the sterilization chambers (there are 11 chambers at the facility) and then to the 5 aeration rooms. The products may stay in the aeration rooms from 8 hours to 23 days, with 48 hours being the most common time period. The last step is a transfer to the "Processed storage" area for shipping back to customers. Mr. Fitzpatrick explained that the sterilization cycles vary according to customers' specifications and can range from 16 hours to 24 days; they currently have 60 different cycles. Sterigenics previously used propylene oxide for sterilization. Mr. Fitzpatrick stated it was last used around 2004-2006. Inspector Sundberg confirmed that NYSDEC was in the process of removing the propylene oxide from the CAA permit.

Inspector Velez then asked about the air pollution control devices for the sterilization process. Mr. Fitzpatrick explained that Sterigenics used a wet scrubber and a catalytic oxidizer. The oxidizer was installed around 1993 and the scrubber in 1995, with an upgrade in 1998 that consisted of extending the stack. The catalyst for the oxidizer was last changed in 2018. The catalytic oxidizer and the scrubber have yearly performance tests. Inspector Velez asked for any other control devices and Mr. Fitzpatrick noted that the company plans a future project of installing 2 dry beds as secondary controls, but the beds were not in service yet. The group then decided to conduct the facility walkthrough.

Mr. Fitzpatrick and the inspectors started the tour at approximately 10:40 am. The group took a quick glance at the preconditioning room and then at the unprocessed warehouse/area. Mr. Fitzpatrick directed the group to the control room where the inspectors could observe the status of the chambers on the screens. The parameters monitored were temperature and pressure. Mr. Fitzpatrick showed the inspectors the gas chromatography (GC) equipment that takes samples every 3 minutes at 16 different ports throughout the facility. The group then walked to the processed warehouse/area and the ethylene oxide drums area. There was one ethylene oxide drum connected to each specific sterilization chamber. The group also inspected the catalytic oxidizer area; the inlet bed temperature was 307 ^{O}F and the oxidizer temperature was 303.9 ^{O}F. The ethylene glycol level in the scrubber was 91 inches at the time of the inspection. The group returned to the break room.

Inspector Velez asked some more questions of Mr. Fitzpatrick. Sterigenics employs 24 people; 11 are operators involved with the ethylene oxide sterilization process. The company operates 24/7 in 4 shifts. The operators have annual physical exams for ethylene oxide exposure monitoring, and basic safety orientation and job-specific trainings. The company has not had any accidental releases of ethylene oxide in the last 5 years. The ethylene oxide is provided by one supplier. The facility acquires between 20,000 to 30,000 lbs of ethylene oxide per month. Inspector Velez also reviewed some of the employee training and orientation forms, the January 2022 to June 2022 semi-annual test report, and the scrubber performance test from September 2021.

Inspector Velez thanked Mr. Fitzpatrick for accommodating the EPA's inspection and noted that the inspectors had not observed any situation that would put human health and the environment at risk during the time of the inspection. Inspector Velez requested a list of documents for review back in the office, which included stack/performance test reports for the catalytic oxidizer and the scrubber, semi-annual reports from January 2020 to June 2022, and records of usage of ethylene oxide. This concluded the inspection, and the inspectors left the facility at approximately 12:15 pm.

Lead Inspector's Name: Julian Velez

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Lead Inspector

Assisting Inspector's Name: Victor Tu

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Assisting Inspector

Supervisor's Name: Nancy Rutherford

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Supervisor